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OIPE IAP91 DEC 21 2007 PATENT & TRADEMARK OFFICE

December 21, 2007

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Art Unit 1617

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Re: U.S. Utility Patent Application
Appl. No. 10/505,137; § 371 Date: August 19, 2004
(*U.S. Nat'l Phase of PCT/GB03/00702; Int'l Filing Date: February 19, 2003*)
For: **Solvent-Based Sterilization Of Pharmaceuticals**
Inventors: BHATARAH *et al.*
Our Ref: 2544.1120000/RWE/SLE

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Reply to Restriction Requirement and Election of Species; and

2. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of the documents and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Robert W. Esmond
Attorney for Applicants
Registration No. 32,893

RWE/SLE:bac
Enclosure

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

OIPE IAP91 DEC 21 2007 PATENT & TRADEMARK OFFICE

In re application of:
BHATARAH *et al.*
Appl. No.: 10/505,137 (*U.S. Nat'l Phase of PCT/GB03/00702; Int'l Filing Date: February 19, 2003*)
§ 371 Date: April 25, 2005
For: **Solvent-Based Sterilization Of Pharmaceuticals**

Confirmation No.: 1688
Art Unit: 1617

Examiner: Jody Lynn Karol
Atty. Docket: 2544.1120000/RWE/SLE

Reply to Restriction Requirement and Election of Species

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the Restriction Requirement dated November 23, 2007, requesting an election of one invention to prosecute in the above-referenced patent application, Applicant hereby provisionally elects to prosecute the invention of Group I, represented by claims 77-103. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

This election is made with traverse.

In reply to the election of species in the same Restriction Requirement, Applicants hereby provisionally elect budesonide. Claims 80, 94-98 and 105 read on such species. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

This election is made with traverse.

The Examiner alleges that the claims are deemed to correspond to "more than one species of the generic invention. These species are deemed to lack unity of invention

because they are not so linked as to form a single general inventive concept under PCT Rule 13.1." (Office Action, page 3, lines 16-18). The Examiner alleges that these species do not relate to a single general inventive concept under PCT Rule 13.1 "because under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species of steroids are known as taught by Karlsson." (Office Action, page 4, lines 14-17). Applicants respectfully traverse.

Firstly, Applicants note that the International Searching Authority ("ISA") determined that there was unity of invention. The ISA was able to examine the full scope of similar claims during the international stage.

Secondly, Applicants respectfully assert that the claims are directed to a single inventive concept. PCT Rule 13.2 permits a group of inventions to be claimed in a single application when "there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." The phrase "special technical features" means "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

The Examiner points to PCT Appl. Pub. No. WO 99/25359 to Karlsson *et al.* (hereinafter "Karlsson") as indication that the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. (Office Action, page 3, lines 8-13). Applicants respectfully disagree. While Karlsson does disclose a sterile formulation comprising a glucocorticosteroid such as fluticasone or budesonide, the disclosure relates to the

preparation of sterile formulations without the use of a solvent. Karlsson discloses that a "method for the production of sterile isotonic solution of medicinal agents, which comprises adding the agent to a saturated solution of sodium chloride in water at 100 °C and then heating the mixture to 100-130 °C" is not suitable "for suspensions of fine particles of glucocorticosteroids which are intended for inhalation because the water, and the heating and cooling involved, produce unfavorable changes in the size of the particle." (Karlsson, page 1, lines 23-27). Furthermore, Karlsson teaches the difficulty in sterilization of a suspension and states that "attempts at terminal sterilization of the pharmaceutical formulations, especially suspensions, e.g., aqueous suspensions, of glucocorticosteroids have all proved unsatisfactory. Such suspensions can not normally be sterilized by sterile filtration as most of the particles of glucocorticosteroid will be retained on the filter." (Karlsson, page 3, lines 8-11). Therefore, Karlsson teaches away from the use of a solvent in the preparation of fine particles of glucocorticosteroids.

Finally, the Manual of Patent Examining Procedure ("MPEP") § 803 (Original Eighth Edition, August 2001, Revision 6, August 2007), states that "[i]f a search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent and distinct inventions." Thus, the Patent Office encourages the search and examination of an entire application on the merits, where such search and examination can be made without serious burden.

It is believed that here, all of the inventions categorized by the Examiner could be searched without undue burden, because a search of the subject matter of species I

(budesonide) would necessarily overlap with a search for the subject matter of species II (fluticasone). Accordingly, it is believed that a search for art relevant to the examination of species I would find art relevant to the examination of the corresponding species II. Thus, both groups can be examined without serious burden.

Reconsideration and withdrawal of the Restriction Requirement, and consideration and allowance of all pending claims, are respectfully requested.

It is believed that extensions of time are not required, beyond those that may otherwise be provided for in accompanying documents. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefore are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

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Date: Dec. 21, 2007

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